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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,506	04/22/2004	Marvin John Cervantes	P1482 US (2650/81)	7331

7590 08/22/2008
MEDTRONIC VASCULAR, INC.
3576 Unocal Place
Santa, Rosa, CA 95403

EXAMINER

RYCKMAN, MELISSA K

ART UNIT	PAPER NUMBER
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3773

MAIL DATE	DELIVERY MODE
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08/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/829,506	Applicant(s) CERVANTES, MARVIN JOHN	
	Examiner MELISSA RYCKMAN	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 April 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/3/08 has been entered.

Drawings

The drawings were received on 4/30/08. These drawings are not accepted, they are not supported by the originally filed application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 5-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification and the drawings fail to show an o-ring having an o-ring diameter wherein a proximal portion of the sleeve is **positioned proximal** to the port vessel. The previous set of claims did not include language for the positioning of the sleeve with respect to the o-ring.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 5-9 recites the limitation "the stent deployment assembly" in the seventh line of claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,5,7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al. (U.S. Patent No. 6,270,521).

Claim 1:

Fischell teaches a system for treating a vascular condition, comprising: a catheter (12); a stent assembly (40) coupled to the catheter; the stent assembly comprising a coated stent including a stent framework and a drug coating disposed on at least a portion of the stent framework (col. 5, ll. 32-34); a protective sleeve (34) removably covering the stent deployment assembly and at least a portion of the catheter, wherein said sleeve comprises a hollow tube having a proximal outer diameter, a medial inner diameter, and a distal inner diameter (fig. 2b); and wherein the distal inner diameter is sufficient to encircle an outer diameter of the stent deployment

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assembly (fig. 2b), and wherein the medial inner diameter is sufficient to encircle an outer diameter of the catheter, and wherein the distal inner diameter is open (fig. 2b), wherein the protective sleeve is removed from covering the stent (fig. 2c) framework prior to deploying the stent, and a port to a vessel (18), the port including an o-ring having an o-ring inner diameter (portion of 18 acts as an o-ring), wherein a proximal portion of the sleeve (34) is positioned proximal to the port vessel and wherein the outer diameter of the proximal portion is greater than the o-ring inner diameter (Fig. 2c).

Claim 5:

Fischell teaches the sleeve comprises a material selected from the group consisting of nylon, polyurethane, polyethylene terephthalate, polyethylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, an elastane, a thermoplastic elastomer, a woven polymeric fabric, or an expandable polymeric sheet (nylon, col. 2, ll. 50-52).

Claims 7 and 8:

Fischell teaches a lubricious coating on at least a portion of a surface of the sleeve (col. 2, ll. 54), the examiner interprets the coating to be a lubricious film.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (U.S. Patent No. 6,270,521) as applied to claim 1 above.

Claim 6:

Fischell teaches the invention as claimed above, however does not specify the sleeve comprising a material that dissolves while in a vasculature. It would have been obvious to one of ordinary skill in the art to use a biodegradable material as it is well known in the art to use a biodegradable material for a stent sleeve, as this omits a surgery to remove the sleeve later on.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. (U.S. Patent No. 6,270,521) as applied to claim 1 above, and further in view of Roberts et al. (U.S. Patent No. 5,984,964).

Fischell teaches the claimed invention above, however does not specify dimensions of the sleeve, however Roberts teaches the sleeve has a distal inner diameter of substantially .071 centimeters, a distal outer diameter of substantially .0825 centimeters (col. 4, ll. 52-59), a medial inner diameter (L7) of .045 centimeters, and a medial outer diameter of .055 centimeters (col. 4, ll. 59-63).

It would have been obvious to one of ordinary skill in the art to have the dimensions of Roberts as these dimensions are appropriate for use in the vasculature.

Response to Arguments

Applicant's arguments filed 4/3/08 have been fully considered but they are not persuasive. The applicant generally argues the following:

- The location of the o-ring is supported in the specification
- Fischell does not teach an o-ring or port

The examiner's position is that page 8, lines 4-7 of the specification simply state "the outer diameter of sleeve 10 is greater than the inner diameter of an o-ring in the Y-arm" the examiner argues, Fig. 1 shows the outer diameter of 10 is smaller than the o-ring. The location of the o-ring is simply "an o-ring in the Y-arm" the location is not specified.

The examiners position is that a portion of element 18 of Fischell, a balloon, acts as an o-ring (the proximal end is a port, the distal end an o-ring). The applicant does not state the structure of the o-ring or the port.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MKR

/Melissa Ryckman/

Examiner, Art Unit 3773

/Darwin P. Erez/

Primary Examiner, Art Unit 3773